

## **MASTER TESTING LIST**

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## Executive Summary

As stated in Section 2 of the Toxic Substances Control Act (TSCA), "It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures."

Section 4 of TSCA gives EPA the authority to require chemical manufacturers and processors to test existing chemicals. Under Section 4, EPA can by rule require testing after finding that (1) a chemical may present an unreasonable risk of injury to human health or the environment, and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the needed data. The Chemical Testing Program in EPA's Office of Pollution Prevention and Toxics (OPPT) also works with members of the U.S. chemical industry to develop needed data via TSCA Section 4 Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually less resource intensive than formal TSCA rule-making and allows EPA to consider agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as a possible substitute for or adjunct to certain types of needed testing.

OPPT has been using the Master Testing List (MTL) since 1990 to establish its TSCA Existing Chemical Testing Program agenda. The MTL presents a consolidated listing of OPPT's existing chemical testing priorities as well as those of other EPA Program Offices, other Federal agencies, the TSCA Interagency Testing Committee, and international organizations such as the Organization for Economic Cooperation and Development (OECD).

The main purposes of the MTL are to (1) identify chemical testing needs of the Federal Government (including EPA) and relevant international organizations (e.g., OECD), (2) focus limited EPA resources on the highest priority chemical testing needs, (3) publicize the testing priorities for industrial chemicals, (4) obtain broad public input on OPPT's TSCA Chemical Testing Program and its priorities, and (5) encourage voluntary initiatives by the U.S. chemical industry to fill the priority data needs that are identified on the MTL.

EPA believes that companies with product stewardship programs will recognize the importance of promptly filling the data needs identified via the MTL because they know a database that is inadequate to support risk assessment deprives people who are exposed to a chemical of their right to know about the hazards/risks that may be posed by that chemical substance. The identification of testing needs on the MTL provides an opportunity for responsible companies to initiate voluntary activities to develop the needed data for their own MTL-listed chemicals. In those instances in which companies decline to take this opportunity, EPA is put in a position of having to initiate formal, resource intensive, regulatory actions such as promulgating TSCA Section 4 Test Rules. Issuance of such rules can be viewed as "forcing" chemical companies to adhere to their own professed standards of product stewardship and corporate responsibility.

The MTL contains over 500 individual existing chemicals and more than 10 existing chemical categories and presents EPA's TSCA Chemical Testing Program priorities for 1996-1998. Testing actions are currently being developed on more than 200 chemicals listed on the MTL while testing is currently underway on almost 300 chemicals identified on the MTL. In addition, more than 100 chemicals are being removed from the MTL at this time, over 70 of those because their testing programs have been completed.

It is also important to note that the Chemical Testing Program and the MTL are integral components of OPPT's TSCA Existing and New Chemicals Programs. These programs are responsible for assessing and managing health and environmental risks that may be posed by existing and new chemicals covered by TSCA. The "universe" of existing chemicals on the TSCA Chemical Substances Inventory that may present the greatest potential health and/or environmental concerns have been and continue to be identified and refined through various existing chemical screening activities within OPPT.

# MASTER TESTING LIST

## Table of Contents

	<u>PAGE</u>
Executive Summary	i
Introduction	1
Additions to the MTL	6
Removals from the MTL	16
Format for the MTL	19
Participating in the TSCA Chemical Testing Program	25
Appendix I. (TSCA Existing Chemicals Program Overview)	27

### Master Testing List Indices

INDEX I. Chemicals Listed on the MTL (Includes Removals)

INDEX II. Chemicals Removed from the MTL (Includes Removal Rationale)



# MASTER TESTING LIST

## Introduction

### Background

Under the Toxic Substances Control Act (TSCA), EPA is given broad authority to issue regulations designed to gather health/safety and exposure data on, require the testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods and food additives, pesticides, and nuclear materials are exempt from TSCA and are subject to control under other Federal statutes (e.g., foods, food additives, drugs and cosmetics are under the purview of the Federal Food, Drug, and Cosmetic Act (FFDCA) which is administered by the U.S. Food and Drug Administration (FDA)).

It is important to note that TSCA has differing mandates regarding the regulations for "existing" chemicals (i.e., those already in U.S. commerce) and "new" chemicals (i.e., those not yet in U.S. commerce). Therefore, when TSCA became effective on January 1, 1977, it was imperative that EPA be able to distinguish between existing chemicals and new chemicals. This was accomplished by using TSCA Section 8(a) information reporting requirements to create the TSCA Chemical Substances Inventory. The TSCA Inventory is a compilation of the names of all existing chemical substances along with their respective Chemical Abstract Service (CAS) Registry numbers and certain other types of information (e.g., production/importation volume ranges, specific sites of production/importation). After 1977, a producer or importer of a "new" chemical (i.e., one that is not listed on the TSCA Inventory) is required to submit a TSCA Section 5 "Pre-Manufacture Notice" (PMN) to the New Chemicals Program in the Office of Pollution Prevention and Toxics (OPPT) in EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS). (For more information about the New Chemicals Program, the reader is directed to an article by Moss et al. which appeared in the January/February 1996 issue of Chemical Health and Safety published by the American Chemical Society.)

The Master Testing List (MTL) is an important component of EPA's Existing and New Chemicals Programs under TSCA. The Existing Chemicals Program is responsible for assessing and managing health and environmental risks that may be posed by existing chemical substances covered by TSCA. The "universe" of existing chemicals on EPA's TSCA Inventory that may present the greatest potential health and/or environmental concerns (including testing needs) have been and continue to be identified and refined through various screening activities within OPPT. This latest version of the MTL also includes priority testing and actions derived from the TSCA New Chemicals Program.

The TSCA Inventory currently contains over 70,000 existing chemicals, many of which are produced or imported at low or negligible volumes, while others are polymers which, because of their physical size (e.g., high molecular weight) and other characteristics, are unlikely to present significant risk concerns. By excluding low volume chemicals (~25,000 chemicals produced or imported in amounts less than 10,000 pounds per year) and polymers (which tend to be poorly absorbed by organisms and therefore typically exhibit low toxicity), the remaining TSCA Inventory is comprised of about 15,000 non-polymeric chemicals produced/imported at levels above 10,000 pounds per year.

Of these 15,000 non-polymeric chemicals, there are 3,000-4,000 chemicals that are produced/imported in amounts over 1 million pounds per year; these chemicals are considered by EPA to be U.S. High Production Volume (HPV) chemicals. EPA has identified this 15,000 chemical subset as being the broad focus "universe" of the TSCA Existing Chemicals and Chemical Testing Programs with the primary focus placed on the 3,000-4,000 HPV chemicals. (See Figure 1.) This screening and testing approach is supported by an U.S. Office of Technology Assessment (OTA) report entitled "Screening and Testing Chemicals in Commerce" (OTA-BP-ENV-166; September, 1995). For more information with regard to the TSCA Existing Chemicals Program, the reader is directed to Appendix I ("EPA's Existing Chemicals Program - An Overview").

#### Chemical Testing Under TSCA

Section 4 of TSCA gives EPA the authority to require chemical manufacturers and processors to test existing chemicals. Under Section 4, EPA can by rule require testing after finding that (1) a chemical may present an unreasonable risk of injury to human health or the environment, and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the necessary data. The TSCA Chemical Testing Program also continues to work with members of the U.S. chemical industry to develop needed test data via TSCA Section 4 Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually much less resource intensive than formal TSCA rule-making and allow the Agency to consider agreed-upon pollution prevention and other product stewardship-related initiatives by the industry as a possible substitute for or adjunct to certain types of needed chemical testing.

Since 1979, approximately 540 of the 15,000 chemical sub-set of the TSCA Inventory have been the subject of testing actions within the OPPT Existing Chemicals Testing Program. Virtually all of the 540 chemicals are "HPV chemicals." The testing actions taken to date include a mix of formal TSCA Section 4 Test Rules and Section 4 Enforceable Consent Agreements, and Voluntary Testing Agreements. More than 50%

of these testing actions have been taken in the last several years and have focussed on chemicals with clearly identified data "needs" (as opposed to simply data gaps). In addition, almost 250 formal TSCA Section 4 "Decisions Not To Test" (DNTs) have been issued by EPA to date. Screening efforts to identify priorities and determine testing needs for other chemicals are currently underway in OPPT.

### Master Testing List

EPA has been using the Master Testing List (MTL) since 1990 to set OPPT's Chemical Testing Program agenda. The MTL presents a consolidated listing of OPPT's existing chemical testing priorities under TSCA and also includes the priority industrial chemical testing needs of OPPTS, other EPA Program Offices (e.g., Office of Air and Radiation, Office of Water), other Federal agencies (e.g., U.S. Occupational Safety and Health Administration, U.S. Consumer Product Safety Commission, U.S. Department of the Interior), and the TSCA Interagency Testing Committee (ITC).

The purposes of the MTL are to (1) identify chemical testing needs of the Federal Government (including EPA) and international programs of interest to the U.S., (2) focus limited EPA resources on the highest priority chemical testing needs, (3) identify and publicize EPA's testing priorities for industrial chemicals, (4) obtain broad public comment on EPA's Chemical Testing Program and its priorities, and (5) encourage voluntary initiatives by members of the U.S. chemical industry to provide EPA with the priority data identified via the MTL as being needed.

Companies with product stewardship programs will recognize the importance of promptly filling the data needs identified via the MTL because they know a database that is inadequate to support risk assessment deprives people who are exposed to a chemical substance of their right to know the hazards/risks that may be posed by that chemical. The identification of testing needs on the MTL provides an opportunity for responsible companies to initiate voluntary data development activities to develop the needed data for their own MTL-listed chemicals. Companies that are good product stewards will carefully evaluate and in many cases voluntarily meet the testing needs identified via the MTL. EPA believes that to the extent companies decline this opportunity, they are not living up to their own professed standards of corporate responsibility. In those instances in which voluntary testing is not undertaken, EPA is put in a position of having to initiate a formal, resource intensive, regulatory action such as promulgating a TSCA Section 4 Test Rule. EPA's issuance of such a rule can be viewed as "forcing" companies to adhere to their own product stewardship principles.

The MTL presents EPA's TSCA Chemical Testing Program priorities for 1996-1998 and includes over 500 individual existing chemicals and more than 10 existing chemical categories. Testing actions are currently being developed on more than 200 of the chemicals listed on the MTL while testing is currently underway on almost 300



other chemicals on the MTL. In addition, over 100 chemicals are being removed from the MTL at this time, more than 70 of those because of completion of their testing programs. It should be noted that a number of chemicals are found more than once on the MTL as the result of different testing actions that have been or are being developed on those chemicals.

This version of the MTL also includes information about EPA's TSCA New Chemicals Program (NCP). The TSCA NCP is responsible for reviewing new chemical substances prior to their entry into U.S. commerce. While testing of new chemicals can be required by way of an action under Section 5(e) of TSCA, the NCP has also had success in developing voluntary testing programs with the affected industry. Many of the new chemicals that have been or are being tested are members of the NCP's "Chemical Categories."

Since 1979, EPA action under TSCA Section 5(e) has resulted in the generation of needed health and/or environmental effects data on over 1000 new chemicals. The required studies have been split evenly between health effects tests and environmental effects tests. Some environmental fate and physical/chemical properties testing has also been required. Additional information about the contributions of the TSCA NCP to the EPA's overall TSCA Chemical Testing Program are expected to appear in future iterations of the MTL.

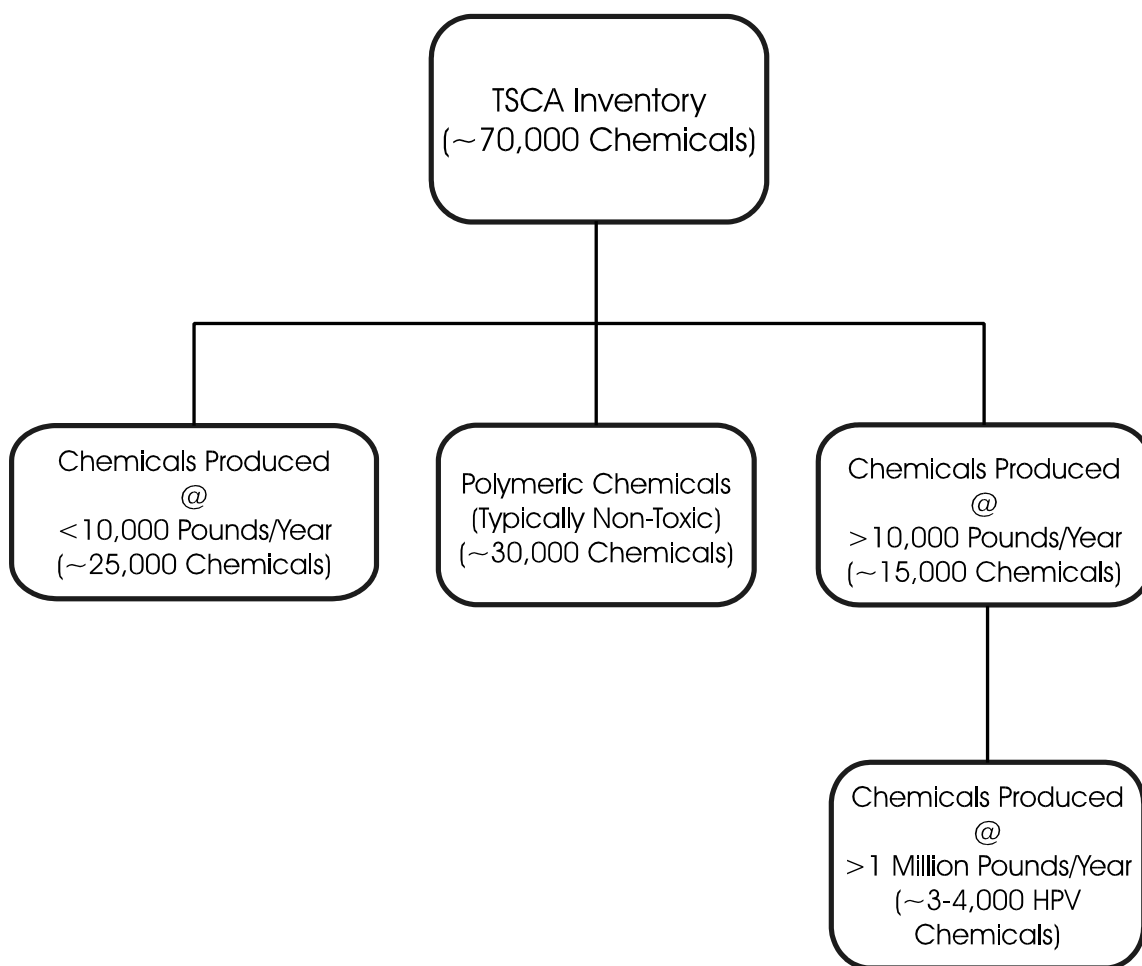


Figure 1. Existing Chemical Universe Chart

## **I. ADDITIONS TO THE MTL SINCE 1992**

### **A. Specific Chemical Substances**

The following provides a brief overview of the specific chemicals that have been added to the MTL since 1992:

- o One-hundred and forty-one (141) chemicals from the international Organization for Economic Cooperation and Development (OECD) "Screening Information Data Set" (SIDS) voluntary testing program;
- o Eighty-three (83) chemicals designated by the TSCA Interagency Testing Committee (ITC) for skin absorption rate testing in its 31st, 32nd and 35th Reports to EPA; however, the designation for 3 of the subject chemicals was subsequently withdrawn by the ITC and the chemicals were removed from the MTL;
- o One (1) chemical (white phosphorus) designated by the ITC for ecological effects testing in its 34th Report to EPA; however, the TSCA Section 4 testing designation for white phosphorus was subsequently withdrawn by the ITC and the chemical was removed from the MTL. In 1996, white phosphorus was added back to the MTL because EPA is trying to obtain ecological effects testing needed by the Department of the Interior via a mechanism other than a formal TSCA Section 4 rule-making activity;
- o Twenty-three (23) chemicals from the EPA Office of Air and Radiation (OAR) Clean Air Act Amendments (CAAA) Section 112 "Hazardous Air Pollutants" (HAPs) category described in Section B. below;
- o Thirteen (13) chemicals (10 organics and 3 metals) from the Agency for Toxic Substances and Disease Registry (ATSDR) Superfund Amendments and Reauthorization Act (SARA) Section 104 category described in Section B. below;
- o One (1) chemical (alkyl C12-C13 glycidyl ether) from the "Glycidol and Its Derivatives" category of chemicals originally designated for health effects testing under TSCA Section 4 by the ITC in its 3rd Report to the EPA Administrator;
- o Four (4) high production volume, high exposure chemicals from the Toxic Release Inventory (TRI) Screening category described in Section B. below;

- o Six (6) siloxanes from a comprehensive industry testing program established via a voluntary "Memorandum of Understanding" (MOU) between EPA and the Dow Corning Corporation;
- o Three (3) dibasic esters (DBEs) used as substitutes for methylene chloride in paint stripping products; the testing action on DBEs, which are among the chemicals in EPA's ongoing assessment of paint stripping products and their components, is being developed at the request of the U.S. Consumer Product Safety Commission (CPSC);
- o Three (3) chemicals from EPA's Office of Air and Radiation (OAR) Oxygenated Fuel Additives (OFAs) category described in Section B. below;
- o One (1) chemical (aniline) from an industry testing program being conducted on a voluntary basis;
- o One (1) chemical (branched 4-nonylphenol) as the result of a formal OPPT TSCA Existing Chemical Program Risk Management (RM-1) disposition;
- o Five (5) chlorofluorocarbon substitutes from EPA's TSCA New Chemicals Program (NCP) Chemical Categories described below;
- o Fifteen (15) acrylates/methacrylates from EPA's TSCA NCP Chemical Categories described below;
- o Two (2) fluorescent whitening agents from EPA's TSCA NCP Chemical Categories described below;
- o Two (2) vinyl esters from EPA's TSCA NCP Chemical Categories described below; and
- o Ten (10) peroxides from EPA's TSCA NCP Chemical Categories described below.

## **B. Categories**

The following categories have been targeted by EPA for testing needs and/or testing action development; the categories that are currently on the MTL (including those that have been added to the MTL since 1992) are as follows:

### **1. Persistent Bioaccumulators**

Many chemicals that possess persistent and bioaccumulative properties have been found to present significant environmental problems. Emerging concerns in EPA, especially in the Office of Water, focus on sediments contaminated with chemicals having these characteristics. OPPT plans to require the development of environmental fate and ecotoxicity test data on these chemical substances to support a more comprehensive risk assessment. OPPT is in the process of identifying the set of chemicals that will be addressed under this effort and the types of testing needed.

### **2. New Chemicals Program "Chemical Categories"**

EPA's New Chemicals Program has established 47 chemical categories for which TSCA section 5(e) risk determinations have been made based upon health or environmental concerns identified through structure-activity relationships (SAR). These chemical categories were established to facilitate the TSCA Section 5 "Pre-Manufacture Notice" (PMN) review/regulatory process and represent part of a general effort by EPA to promote development of safer chemicals. EPA is continuing to refine the boundaries and definitions of such categories and engage the chemical industry in dialogue directed toward development of focussed testing programs on commercially promising new chemicals and/or structurally-related existing chemicals. The resulting test data are valuable to EPA as well as the industry for hazard identification, risk management, and the design of safer substitutes. Properly conducted, strategic testing of one or more members of a category can often be used to evaluate the toxicologic potential of an entire class of commercially promising compounds from that category. The following discussion provides a brief overview of the OPPT New Chemicals Program "categories" that are now listed on the MTL, namely: Chlorofluorocarbon Substitutes, Acrylates/Methacrylates, Vinyl Esters, Fluorescent Whitening Agents, and Peroxides.

#### **a. CHLOROFLUOROCARBON SUBSTITUTES**

Since 1989, OPPT's New Chemicals Program has been working closely with EPA's Office of Air and Radiation (OAR) to 1) coordinate identification of and provide a more thorough and consistent EPA review of health and

environmental effects of "new" chemical substances that can be used as substitutes for ozone-depleting chlorofluorocarbons (CFCs); and 2) develop regulatory strategies for controlling commercial introduction of these substitutes in order to address toxicological concerns as well as OAR issues such as ozone depletion and global warming. OAR participates in OPPT's New Chemicals Program process at the earliest review stages and regulatory strategies are developed to meet the requirements of both the Toxic Substances Control Act (TSCA) and the Clean Air Act (CAA). Among the regulatory tools used by OPPT in dealing with "new" CFC substitutes are "Consent Orders" issued under Section 5(e) of TSCA. Section 5(e) Consent Orders are developed to require the manufacturer or importer of a new CFC substitute to control exposure to that chemical and/or conduct additional testing on that material. Another TSCA regulatory tool that is used is the Section 5 "Significant New Use Rule" which covers potential additional producers/importers and users of that CFC substitute and may subject "new" uses of the chemical to further EPA review and/or control. Interactions between OPPT and OAR have reduced duplicative review efforts resulting in substantial resource savings for EPA while industry benefits from a coordinated regulatory program that simultaneously addresses the concerns of both EPA offices. In order to supply EPA with needed toxicological data to assess the potential hazards that may be posed by exposure to CFC substitutes, and in addition to conducting toxicity studies that are required by EPA via TSCA Section 5(e) Consent Orders on 3 "new" CFC substitutes, the chemical manufacturers who are members of the international Program for Alternative Fluorocarbon Toxicity (PAFT) agreed in the late 1980's to conduct a comprehensive voluntary testing program on two existing chemical substitutes (namely, 1,1,1,2-tetrafluoroethane [HFC-134a] and 2,2-dichloro-1,1,1-trifluoroethane [HCFC-123]). The PAFT testing program was reviewed and accepted internationally by authorities in the U.S., the European Union and Japan. This understanding provided additional certainty to industry developing these chemicals. PAFT's voluntary testing program is still underway and includes studies designed to develop data on genotoxicity, acute toxicity, subacute toxicity, subchronic toxicity, neurotoxicity, reproductive/developmental toxicity, and oncogenicity. In addition to conducting these toxicological studies on a voluntary basis, PAFT has been distributing copies of the study reports publicly on a world-wide basis.

#### **b. ACRYLATES/METHACRYLATES**

Based on cancer concerns, "new" chemical substances in the category of acrylates (including methacrylates) are being regulated by EPA under Section 5 of TSCA. Following discussions with OPPT staff regarding these regulations, the industry members of the Specialty Acrylates Manufacturers (SAM) offered to conduct a voluntary testing program on 13 "existing" acrylates in exchange for

some concessions by EPA in regulating new acrylates under Section 5. As the result of negotiations with SAM, OPPT agreed not to require a cancer warning on product labels for new acrylates regulated by EPA; however, cancer warnings, would still appear on the Material Safety Data Sheets (MSDSs) for these chemicals. For its part, SAM agreed in 1990 to conduct a voluntary testing program involving physical/chemical properties and metabolism/pharmacokinetics testing on 13 existing acrylates and cancer bioassays on 2 of those chemicals. SAM's voluntary testing program was completed in September of 1995 and the results of the tests are currently under review by OPPT.

**c. VINYL ESTERS**

A vinyl ester is a carboxylic acid ester with at least 1 vinyl group ( $\text{CH}_2=\text{CH}-$ ) attached to an organic acid radical ( $\text{RCOO}-$ ). In 1992, the chemical industry initiated a testing program designed to evaluate a new generation of vinyl esters submitted to EPA's New Chemicals Program under Section 5 of TSCA. These vinyl esters are being developed to replace lower molecular weight acrylates (see preceding discussion on Acrylates/Methacrylates). The testing program includes glove permeation, hydrolysis, non-protein sulfhydryl ("GSH") depletion, subchronic toxicity, and developmental toxicity studies as well as cancer bioassays. EPA responded to this industry initiative by agreeing not to require cancer warnings on product labels for new vinyl esters regulated by the Agency under TSCA Section 5 (although cancer warnings still appear on the Material Safety Data Sheets (MSDSs) for these chemicals).

**d. FLUORESCENT WHITENING AGENTS**

In EPA's TSCA Section 5 New Chemicals Program, fluorescent whitening agents fall under the general chemical category of water soluble (sulfonated) derivatives of 4,4-bis(triazin-2-ylamino)stilbene. Testing program negotiations are currently underway with members of the Ecological and Toxicological Association of Dyestuffs and Organic Pigments Manufacturers (ETAD) to conduct needed developmental and reproductive toxicity studies on at least 2 representative stilbene-based fluorescent whitening agents.

**e. PEROXIDES**

A molecule containing one or more of the following functional groups is considered by the TSCA Section 5 New Chemicals Program to be a member of the "peroxides" category: dialkyl peroxide, alkyl hydroperoxide, peroxy ester, diacyl peroxide and peroxy acid. The typical "new" peroxide is a discrete (Class I) chemical with a molecular weight of less than 500. The chemical industry is

currently developing and conducting a number of short term tests to predict/assess potential tumor promoting and/or carcinogenic activities of 10 organic peroxides. The test systems being developed are: (1) test tube (in vitro) assays for detecting free radical formation, and (2) mouse skin assays for sustained inflammatory/hyperplastic response. In addition to the test tube assays, EPA has suggested use of a human skin cell culture to look for evidence of free radical formation. A series of structurally different new and existing peroxides are being studied in this voluntary testing program and the results are expected to allow correlation of the types and levels of free radicals formed and how damage caused by free radicals may relate to either tumor promoting and/or carcinogenic activity or inactivity.

### **3. EPCRA Section 313 ("TRI Screening")**

The Toxics Release Inventory (TRI) was established under section 313 of the "Emergency Planning and Community Right-to-Know Act" (EPCRA). Under a voluntary cooperative effort with the Chemical Manufacturers Association (CMA) and possibly other chemical trade associations, a subset of at least 10 TRI chemicals produced and released in high volumes will be evaluated and screening level testing developed using the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) model. Thus far, the U.S. chemical industry has agreed to conduct SIDS testing on 4 TRI chemicals. EPA has asked the industry to complete its commitment by selecting at least 6 more "high production/high release" TRI chemicals for SIDS testing.

### **4. Clean Air Act Section 112 "Air Toxics" (Hazardous Air Pollutants)**

Data are needed by EPA's Office of Air and Radiation (OAR) and Office of Research and Development (ORD) to determine the "residual risk" posed by the 189 chemicals (Hazardous Air Pollutants (HAPs)) listed under section 112 of the Clean Air Act Amendments of 1990. The MTL now includes the initial list of 23 chemicals from this category for which testing has been proposed under Section 4 of TSCA (see 61 FR 33178; June 26, 1996). Testing needs for other chemicals in this category are currently being determined in a cooperative effort between OPPT, OAR and ORD. EPA's primary use of the data from this testing activity will be to implement several provisions of section 112 of the Clean Air Act (CAA), including determining residual risks (e.g., assessing risks remaining after imposition of technology-based emission standards (maximum achievable control technology standards or "MACT" standards)), estimating risks associated with accidental chemical releases, and determining whether or not subject chemicals should be removed ("delisted") from the CAA section 112(b) HAPs list. Other important uses of the data obtained via this testing activity are to: 1)



help in better informing communities and citizens about chemical hazards in their own localities, 2) assist state and local permitting authorities establish appropriate standards within their programs, and 3) help other EPA Program Offices and other Federal agencies in assessing chemical risks and taking appropriate action(s) within their own programs and under the Federal statutes that they administer.

## **5. SARA Section 104 "Priority Data Needs"**

Section 104 of the Superfund Amendments and Reauthorization Act (SARA) requires EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) to list chemicals frequently identified in Superfund sites. ATSDR is charged with preparing "Toxicological Profiles" for these chemical substances, identifying data gaps and research needs, and developing a testing/research program. When and where appropriate, EPA's TSCA (or Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)) authorities are to be used to obtain the necessary data. There are 250 chemicals and categories now listed under SARA Section 104 and Toxicological Profiles have been published or are being prepared by ATSDR on 215 of these chemicals and categories. ATSDR has identified priority data needs for the first subset of 13 chemicals (3 metals and 10 organics). These chemicals are listed on the MTL and testing needs/testing action development is currently underway in EPA's Chemical Testing Program.

## **6. Respirable Fibers**

Man-made and naturally-occurring fibers with diameters less than 3.5 micrometers that can enter the small airways of the lower respiratory tract and survive in biological systems for long periods of time can present significant health concerns. EPA is assessing the potential risks associated with the production and use of synthetic and naturally-occurring respirable fibers and products made from such fibers. The testing likely to be proposed by EPA will focus on health effects via inhalation and better characterization of exposure.

## **7. Indoor Air Source Characterization - Carpet/Carpet-Related Products**

An agreement with industry has been reached to generate the test data needed for characterization of Total Volatile Organic Compound (TVOC) emissions from carpets and carpet-related products (i.e., carpet cushion and carpet adhesives). The emissions testing program was developed via EPA's Carpet Policy Dialogue and testing was initiated in 1991 (See 56 FR 67317; December 30, 1991). The final results from the carpet TVOC study have been received by EPA and this entry (Carpet-TVOC) has been removed from the MTL. The voluntary testing programs for both carpet cushion and carpet adhesives are still underway.

## **8. Indoor Air Source Characterization - Interior Architectural Coatings**

OPPT and EPA's Office of Air and Radiation (OAR) are continuing to coordinate efforts to characterize and determine specific needs for chemical emissions and total emissions testing for indoor air sources such as paints, varnishes and other types of interior architectural coatings.

## **9. Polychlorinated Dioxins/Furans in Wood Pulp/Paper Mill Sludge**

Polychlorinated dioxins and furans (D/F) are produced when wood pulp is bleached with chlorine or chlorine-derivative compounds. The sludge that results from the wastewater treatment process in pulp and paper mills has been found to be contaminated with D/F. EPA has identified concerns for possible adverse human health and environmental risks posed by the disposal of this sludge through land application and has determined that additional testing and monitoring data to evaluate such risks are needed. Under the terms of a voluntary agreement with EPA, four pulp and paper mills are evaluating their sludge for D/F concentrations and are engaged in numerous other types of product stewardship activities (e.g., labeling, modifying land application practices). Under the terms of another voluntary agreement with EPA, the American Forest and Paper Association is collecting, aggregating and submitting data from the mills to EPA and coordinating industry's outreach efforts on this voluntary testing/stewardship program.

## **10. Endocrine Disruptors (New Category)**

Endocrine disruptors are chemicals that interfere with normal hormone system functioning. These substances can have adverse impacts on growth and development, sexual differentiation, and a host of biological functions that are controlled through the endocrine system. One of EPA's primary efforts for endocrine disruptors involves the establishment of a dialogue with industry and other major stakeholders (including other Federal agencies) to formulate a cooperative screening and testing program designed to identify chemicals that can disrupt endocrine function(s) and determine the risk they may pose to health and/or the environment. In addition, Section 405(p) of the 1996 Food Quality Protection Act (FQPA) requires that EPA develop (within 2 years) and implement (within 3 years) an estrogenic effects screening program for all pesticides using validated test methods. The FQPA also gives EPA the authority to require testing of other chemicals "that may have an effect that is cumulative to an effect of a pesticide." The FQPA states that data can be obtained via Section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Section 4 of TSCA, or an "order" if it can be shown that neither FIFRA nor TSCA

can be applied. Similarly the newly amended Safe Drinking Water Act (SDWA) gives EPA authority to require testing of substances found in drinking water and to which there may be substantial exposure.

#### **11. Machining Fluid Products/Chemicals (New Category)**

Machining fluids, which are also known as metalworking fluids, are used to lubricate and cool industrial equipment and the metal being shaped during a variety of machining operations. These activities include metal removal operations such as cutting or drilling and metal forming operations such as stamping or drawing. The exposure to metalworking fluids is primarily occupational and recent estimates indicate that up to 10 million workers may be exposed to these types of products, primarily via inhalation and dermal contact with mists. There may be as many as 400 different commercial products belonging to one or more of the four major metalworking fluid types: straight oils, soluble oils, semi-synthetics and synthetics. All but the synthetic fluids contain mineral oil as a component and there are no standard formulations of chemical components among commercially available machining fluids. In response to a TSCA Section 21 petition that was filed by the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America-UAW (UAW), EPA formed an interagency workgroup with the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) to identify specific testing candidates and testing needs for machining fluids. In addition, the Federal workgroup has begun discussions with the UAW, the Independent Lubricant Manufacturers Association (ILMA), and others regarding development and implementation of a testing program for machining fluid products and their components.

#### **12. Paint Stripping Products Use Cluster (New Category)**

In 1993, OPPT concluded a risk assessment on N-methyl pyrrolidone (NMP), a methylene chloride substitute in some paint stripping products, and, as a followup to that assessment, began a more broad-based assessment of paint stripping chemicals/products that are commonly available to consumers. As the result of concerns that were raised by EPA and others, and in recognition of the tenets of product stewardship, the NMP Producers Group spearheaded a voluntary effort by the "Ad Hoc Industry Committee for Safe Paint Stripping" to design and conduct a glove permeability testing program. Under this program, numerous glove types are being tested against a variety of paint stripping formulations used by consumers and small paint stripping shops. This voluntary testing program is designed to assess the effectiveness of dermal protection offered by gloves of the type commonly available to consumers through hardware stores. After the testing program is completed, the industry plans to

incorporate the results of the glove permeability testing in improved product labels and other consumer education materials. In addition, EPA is developing a testing action for the U.S. Consumer Product Safety Commission (CPSC) on the following 3 dibasic esters (DBEs) which are used as substitutes for methylene chloride in commercial paint stripping products: dimethyl adipate, dimethyl succinate, and dimethyl glutarate. The data from the DBEs testing program will also be used to support OPPT's ongoing assessment of paint stripping products and their constituents.

### **13. Oxygenated Fuel Additives (New Category)**

EPA's Office of Air and Radiation (OAR/EPA) in the administration of section 211 of the Clean Air Act (CAA), has requested OPPT to use its TSCA section 4 testing authority to obtain health effects data on a number of Oxygenated Fuel Additives (OFAs) such as ethyl t-butyl ether (ETBE) and t-amyl methyl ether (TAME)). These data are needed by EPA and others to increase understanding of the toxicity of these substances individually and in comparison to each other as well as to other OFAs such as methyl t-butyl ether (MTBE). EPA is also currently exploring options for obtaining toxicity data on diisopropyl ether (DIPE) and t-butyl alcohol (TBA) before these chemicals come into wide use as OFAs. In addition, EPA is attempting to obtain test data needed by OAR on t-butyl formate (TBF), which is a possible breakdown product of MTBE.

## II. CHEMICALS REMOVED FROM THE MTL

Since formal issuance of the last MTL in 1992, more than 100 chemical substances have been removed from the MTL for a variety of reasons. The primary reason for removal is that EPA has received, reviewed and accepted the results of all required or agreed-upon testing. This is the case for more than 70 chemicals removed from the MTL since 1992. The list of all of the chemicals removed from the MTL and the rationale for their removal is found in INDEX II. The following discussion provides a brief overview of the individual chemicals and chemical categories that have been removed from the MTL since 1992 because they completed their respective testing programs.

Twenty-one (21) chemicals have completed their testing programs under TSCA Section 4 Final Rule-Making (FRM), including:

Nine (9) chemicals tested as the result of EPA's TSCA Section 4 Halogenated Dioxins/Furans Test Rule:

1,2-Bis(2,4,6-tribromophenoxy)ethane

Decabromodiphenyl ether

Octabromodiphenyl ether

Pentabromodiphenyl ether

Tetrabromobisphenol A

Tetrabromobisphenol A allyl ether

Tetrabromobisphenol A bis(ethoxylate)

2,4,6-Tribromophenol

3,4',5-Tribromosalicylanilide

Ten (10) chemicals formally designated for testing by the TSCA Interagency Testing Committee (ITC):

1,2,4-Trichlorobenzene (3rd ITC Report)

Mesityl oxide (4th ITC Report)

o-Phenylenediamine (6th ITC Report)

m-Phenylenediamine (6th ITC Report)

Vinyl fluoride (7th ITC Report)

Vinylidene fluoride (7th ITC Report)

Commercial hexane (16th ITC Report)

Tributyl phosphate (18th ITC Report)

Methyl ethyl ketoxime (19th ITC Report)

Isopropanol (20th ITC Report)

Two (2) chemicals (1,1,2,2-tetrachloroethane and 1,3,5-trimethylbenzene) from EPA's TSCA Section 4 Office of Drinking Water Test Rule.

Seven (7) chemicals have completed their testing programs under TSCA Section 4 Enforceable Consent Agreements (ECA), including 6 chemicals that were formally designated by the ITC for testing under Section 4 of TSCA:

4-Nonylphenol (branched)

1,1,1-Trichloroethane (2nd ITC Report)

Methyl t-butyl ether (20th ITC Report)

Crotonaldehyde (22nd ITC Report)

Acrylic acid (27th ITC Report)

4-Vinylcyclohexene (27th ITC Report)

Sodium cyanide (27th ITC Report)

Forty-nine (49) chemicals have completed their testing programs as the result of Voluntary Testing Agreements (VTA) including:

Fifteen (15) acrylates/methacrylates from the TSCA New Chemicals Program "Chemical Categories"

Thirty-two (32) chemicals from the OECD/SIDS testing program

One (1) chemical (antimony trioxide) from an industry sponsored, voluntarily conducted epidemiological study; this chemical had originally been designated for TSCA Section 4 testing in the ITC's 4th Report).

A voluntary industry-sponsored "Total Volatile Organic Chemicals" (TVOC) emissions testing program has been completed on carpets; voluntary TVOC emissions testing for carpet cushions and carpet adhesives is still underway.

All of the data from completed chemical testing programs are referred for disposition to EPA's TSCA Existing Chemicals Program "Risk Management" (RM) process (see Appendix I). For information about public participation in the TSCA Chemical Testing Program (including information concerning public access to chemical testing data), the reader's attention is directed to Part IV of this Introduction.

### III. FORMAT, HEADINGS AND CODES FOR 1996-1998 MTL

The MTL is reflected in 2 complementary indices. The first index ("INDEX I. MASTER TESTING LIST") is a "master" index of all chemicals and categories currently on the MTL as well as those chemicals/categories that have been removed from the MTL since 1992. The second index ("INDEX II. CHEMICALS REMOVED FROM THE MTL") includes only those chemicals that have been removed from the MTL since 1992 and provides the rationale for their removal. All of the chemicals on the MTL indices are ordered by ascending Chemical Abstract Service (CAS) Registry Numbers. Those chemicals and categories that do not have CAS Numbers appear at the beginning of each index. A description of the index columns as they are ordered from left to right follows.

**CAS No.:** This unique identifier of up to 9 digits is assigned to chemicals by the Chemical Abstract Service (CAS). CAS Numbers are not available for several chemical substances (e.g., commercial hexane) nor are they available for the categories listed on the MTL. As stated above, chemicals lacking CAS numbers, as well as categories (which have no CAS Numbers), are found at the beginning of each index.

**Chemical Name:** The common chemical name used by EPA.

**Source:** The chemicals/categories on the MTL have been recommended for testing by sources from within EPA, other Federal agencies, the TSCA Interagency Testing Committee (ITC), and the international toxics community. For a number of chemical substances, there are several sources of the testing recommendations identified. All of the sources are listed separately in each of the MTL indices and include the following:

**ATSDR** - U.S. Agency for Toxic Substances and Disease Registry

**CPSC** - U.S. Consumer Product Safety Commission

**DOI** - U.S. Department of the Interior

**ITC** - TSCA Interagency Testing Committee (ITC). The ITC was created under section 4 of TSCA and is mandated to recommend chemical substances to EPA for testing consideration. The ITC recommends these chemicals in twice-yearly formal reports to the EPA Administrator. This code also indicates the ITC Report number in which the chemical was designated for testing. For example, the source code "ITC/16" indicates that the subject chemical substance was designated for testing consideration in the ITC's 16th Report to the EPA Administrator.

**OAR** - Office of Air and Radiation, US EPA



**HAP** - Hazardous Air Pollutants

**OFA** - Oxygenated Fuel Additives

**OECD** - Organization for Economic Cooperation and Development. OECD member nations have agreed that certain international high production volume chemicals should have a "base set" of screening level test data. This base set is referred to as the Screening Information Data Set (SIDS).

**Country:** This column identifies the OECD member country or countries sponsoring the international high production volume chemicals that have been selected for SIDS testing. Under this voluntary program, the sponsor first prepares a data summary or "Dossier" and then conducts testing designed to provide the missing SIDS data. Countries handling the chemicals are identified by 2-letter codes. These codes and their corresponding countries are listed in Table 1. For those chemicals being handled under the European Union's testing program, the code "EU" appears. For those chemicals selected for Post-SIDS testing, the acronym "BIAC" appears in place of the sponsoring country and refers to the OECD's "Business and Industry Advisory Committee."

Table 1. OECD and EU Countries and Codes

OECD COUNTRY	COUNTRY CODE
Australia	AU
Austria*	AT
Belgium*	BE
Canada	CA
Switzerland	CH
Germany*	DE
Denmark*	DK
Finland*	FI
France*	FR
Italy*	IT
Japan	JP
Netherlands*	NL
Norway	NO
Spain*	SP
Sweden*	SE
United Kingdom*	UK
United States	US
*European Union Members  Other EU Member Countries:  Greece Ireland Luxembourg Portugal	EU

**OPPT** - Office of Pollution Prevention and Toxics, USEPA. OPPT has identified existing chemical substances and categories of chemicals in need of testing through its TSCA Existing Chemicals Program and also via its TSCA New Chemicals Program. Those chemicals and categories of chemicals of specific interest to OPPT are found in the following testing actions that are listed on the MTL:

- o Aniline/Substituted Anilines (**ASA**)
- o Carpet/Carpet Products (**CCP**)
- o Dioxins/Eurans in Organic Chemicals Rule (**DF-OC**);
- o Dioxins/Eurans in Pulp and Paper Mill Sludge (**DF-PPMS**);
- o Endocrine Disruptors (**ED**)
- o Formaldehyde (**F**)
- o Interior Architectural Coatings (**IAC**)
- o Machining Eluids (**MF**)
- o Neurotoxicity Endpoint Rule (**N**);
- o New Chemicals Program (**NCP**) "Chemical Categories"
  - o Chlorofluorocarbon Substitutes (**CFCS**)
  - o Fluorescent Whitening Agents (**FWA**)
  - o Acrylates (**ACR**)
  - o Vinyl Esters (**VE**)
  - o Peroxides (**PEROX**)
- o Nonyl Phenol (**NP**)
- o Paint Strippers (**PS**) - DiBasic Esters (**DBE**)
- o Persistent Bioaccumulators (**PBA**)
- o Reproductive/Developmental (**RD**) Toxicity Endpoint Rule;
- o Respirable Fibers (**RF**)

- o Siloxanes (**SILOX**)
- o Toxic Release Inventory (**TRI**) Chemicals

**OW** - Office of Water, USEPA.

- o Office of Drinking Water (**ODW**) Chemicals

**Year Added or Removed:** The year in which a chemical substance or category was added to or removed from the MTL.

**Status:** One of the following program status codes accompanies each of the chemicals or categories listed on the MTL:

**TNDU:** Testing Needs Development Underway - indicates that EPA is in the process of determining the testing needs for a given chemical or chemicals within a listed category. Upon identification of specific testing needs, EPA initiates development of a testing action for the subject chemical(s) or category as described in the following paragraph.

**TADU:** Testing Action Development Underway - indicates that EPA is initiating development of a testing action via TSCA Section 4 Final Rule-Making (**FRM**), a TSCA Section 4 Enforceable Consent Agreement (**ECA**), or a Voluntary Testing Agreement (**VTA**).

**CTPU:** Chemical Testing Program Underway - CTPU indicates that the chemical testing program is currently underway by way of an FRM, ECA, or VTA.

**Removed:** Removed from MTL - "Removed" indicates that the subject chemical substance or category has been deleted from the MTL and the year of the removal. If Index I. indicates that a chemical or category has been removed from the MTL, Index II. (which is a list of those chemicals or categories removed from the MTL since 1992) should be consulted for the specific rationale for that removal. The rationale and additional comments regarding the subject chemical appear in the far right columns in Index II.

**Testing Needs:** The last 3 columns of Index I. indicate specific testing needs for health effects (Health), environmental effects (Environ) and environmental fate/exposure (Fate). Table 2. below lists the codes for specific testing needs for the individual chemicals and categories listed on the MTL.

Table 2. Testing Need Codes

Health Effects		Environmental Effects		Environmental Fate	
ACUTE	Acute toxicity	ACUTE	Acute toxicity	BIOC	Bioconcentration
CARC	Carcinogenicity	CHR	Chronic toxicity	DEGR	Biodegradation
CHR	Chronic Toxicity	SIDS	Screening Data	MONIT	Monitoring
DEVEL	Developmental Toxicity	OTHR	Other	PCHM	Physical Chemical Property
DNEURO	Developmental Neurotoxicity			TSPT	Transport/Transformation
EPID	Epidemiology			SIDS	Screening Data
IMMUN	Immunotoxicity				Exposure Monitoring
MUTA	Mutagenicity				Product Analysis
NEURO	Neurotoxicity			OTHR	Other
PK	Pharmacokinetics				
PCHR	Prechronic Toxicity/14-28 day				
REPRO	Reproductive Toxicity				
SCHR	Subchronic Toxicity/90 day				
SIDS	Screening Data				
	Skin Absorption Rate				
OTHR	Other				

## **IV. PARTICIPATING IN EPA'S CHEMICAL TESTING PROGRAM**

### **How to Submit Information and Comments**

Comments/suggestions for future versions of the MTL should be submitted in triplicate to EPA's TSCA Public Docket (7407), Attn: TSCA Section 4 Master Testing List (OPPTS-00200), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460. Comments that are sent via electronic mail to EPA's TSCA Non-Confidential Information Center (NCIC) should include reference to the TSCA Section 4 MTL (OPPTS-00200) and be sent to:

**[ncic@epamail.epa.gov](mailto:ncic@epamail.epa.gov)**.

Electronic comments and data must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. No TSCA Confidential Business Information (CBI) should be submitted electronically. Electronic comments concerning the MTL may be filed online at many Federal Depository Libraries.

### **How to Obtain Additional Information**

For further information regarding the MTL or EPA's TSCA Chemical Testing Program, contact Ms. Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460, or call the TSCA Hotline at (202) 554-1404, TDD (202) 554-0557. The TSCA Hotline can also be contacted by using the following electronic mail (e-mail) address:

**[TSCA-Hotline@epamail.epa.gov](mailto:TSCA-Hotline@epamail.epa.gov)**

Further information about the TSCA Existing Chemical Testing and Information Gathering Programs can also be obtained from EPA's World Wide Web/Internet site by using the following Uniform Resource Locator (URL):

**<http://www.epa.gov/opptintr/main/ctibhome.htm>**

EPA is making test results and the results of the Agency's review of test data available to the public through summaries that are added to TSCATS (TSCA Test Submissions), a publicly accessible computerized data base. In addition, information about testing decisions resulting from Risk Management (RM) meetings are contained in the administrative record, a central collection point established by OPPT for materials on each chemical handled by OPPT's Existing Chemical Program. Contents of the administrative record include the following items:

- o a screening dossier containing relevant exposure and hazard information, recommendations from the screening work group, and the supporting rationale for that decision;
- o summaries of major studies cited in the screening dossier;
- o summaries of RM meetings;
- o any letters of concern sent by EPA to industry or others and replies received by the Agency; and
- o comments or correspondence received from other interested parties outside EPA.

The public can access OPPT's public docket and administrative record in person, by going to Room B-607 of the Northeast Mall, EPA Headquarters, located at 401 M Street SW, Washington, D.C. from 12:00 Noon to 4:00 PM, Monday-Friday except legal holidays (photocopy facilities are available), or by writing to the TSCA Public Docket (7407), Attention: TSCA Existing Chemicals Program RM Process, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460.

## APPENDIX I. EPA'S EXISTING CHEMICALS PROGRAM: AN OVERVIEW

The U.S. Environmental Protection Agency's (EPA) Existing Chemicals Program gathers hazard and exposure data, screens for hazards/risks, identifies testing needs and establishes testing requirements. The Program also evaluates and develops strategies for preventing pollution and reducing the risks associated with chemicals currently in production or use in the U.S. OPPT's risk management and pollution prevention initiatives can be either regulatory or non-regulatory; all, however, are aimed at reducing or eliminating the likelihood of harm to health and the environment. The Chemical Testing Program is a major component of the Existing Chemicals Program.

Risk management activities in the Existing Chemicals Program are divided into *RM1*, *RM2* and *Post-RM2* stages. *Risk Management 1 (RM1)* is the first stage and is designed to screen and select chemicals that appear to be of greatest concern to human health and the environment and takes about 6 months; identification of additional testing needs is a possible RM1 outcome. *Risk Management 2 (RM2)* is the next step, and takes 12 to 24 months. At the RM2 stage of the process, chemicals identified in RM1 are investigated and analyzed, and options which may include identification of additional testing needs are framed for reducing or eliminating the risks those chemicals pose. *Post-RM2*, which can range between 3 months and 2 years, consists of the implementation of one or more of the risk reduction and/or testing options identified during RM2.

While the Existing Chemicals Program is located in the Chemical Control Division (CCD) of the Office of Pollution Prevention and Toxics (OPPT), contributions to the Program come from all parts of OPPT. This collaborative approach allows pursuit of a wide array of cases. The Existing Chemicals Program currently draws most of its cases from about 15,000 non-polymeric chemicals produced or imported at more than 10,000 pounds per year. The remaining 55,000 of the 70,000 existing chemicals listed on the TSCA Chemical Substances Inventory are either produced or imported at less than 10,000 pounds per year, if at all, or are polymers, which because of their chemical properties, are not considered likely to present a significant risk of injury to health or the environment. Between 1993 and 1996, the Existing Chemicals Program has screened approximately 2000 chemicals in RM1.



There are many ways in which government, industry and other stakeholders can work together to meet the nation's environmental goals. In the past, EPA has relied heavily on regulation to accomplish these goals. We are now recognizing that more cooperative methods are often more efficient and effective. Although regulation under TSCA is still a viable tool and is used when necessary, the Existing Chemicals Program is increasingly turning to cooperative and voluntary methods as first approaches to reducing or eliminating the likelihood of harm to human health and the environment. For further information about OPPT's Existing Chemicals Program in general or the Chemical Testing Program specifically, interested persons should contact the TSCA Hotline at (202) 554-1404, TDD (202) 554-0557. EPA's TSCA Hotline can also be reached at the following electronic mail (e-mail) address:

**TSCA-Hotline@epamail.epa.gov**

A schematic diagram of OPPT's TSCA Existing Chemicals Program (including the Chemical Testing Program) operations is shown in Figure 2.

Figure 2. EPA's TSCA Existing Chemicals Program

